REMARKS

Claims 1-23 are pending herein. Claims 1, 6 and 7 have been amended. Claim 23 has been added.

Support for the amendment to claims 1, 6 and 7 can be found, for example, in the specification in paragraphs [0008] and [0009] and in original claims 8-10. Support for new claim 23 can be found, for example, in paragraph [0024] of the specification.

Claims 1-5 and 7-21, 35 U.S.C. 103(a)

Claims 1-5 and 7-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Umemura et al. US 4,902,503 (Umemura) in view of Trogolo et al US 2003/0118664 (Trogolo) and McGlothlin et al. US 6,329,444 (McGlothlin). This rejection and its accompanying remarks are respectfully traversed.

The present invention is directed to medical articles that comprise an antimicrobial region, which antimicrobial region comprises release-modulating *dispersed microparticles* within a latex polymer. The release-modulating microparticles comprise an antimicrobial agent and are adapted to release the antimicrobial agent.

Umemura discloses two types of antimicrobial latex compositions. The first type contains a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver. That type utilizes a latex, e.g., natural rubber latex, and a silver protein complex, protein-silver, *dissolved* in the aqueous phase of the latexes. See the Abstract, column 2, line 60, column 4, lines 45-48, column 4, 54-57 and column 5, lines 54-56. Thus, it is clear from the disclosures referred to that the protein silver is *required* by Umemura to be water soluble.

The second type uses a homogeneous blend of a cationic natural or synthetic rubber and soluble silver compounds, e.g., silver nitrate, among others. See, e.g., Abstract and column 4, lines 49-53. As with the protein silver, the water-soluble silver compounds are *dissolved* in the aqueous phase. See, e.g., column 8, lines 41-42. Umemura lacks any teaching of "release-modulating *microparticles* disposed within a latex polymer," as claimed. To the contrary, it is essential that the antimicrobial compound be *dissolved* in the aqueous phase of the latex.

In this regard, Umemura notes at col. 2, lines 18-31 that a latex, such as a natural rubber latex dispersed in water, is a highly unstable system. Consequently, when an aqueous solution containing a highly soluble silver compound is added to a latex at a high concentration in order

to give a high silver concentration in the resulting matrix material, the silver nitrate would break the system. Moreover, when silver carbonate, which has an extremely low solubility in water, is added, the stable latex dispersion system is also broken and aggregation is observed. Therefore, it has been impossible to obtain a stable latex composition.

This is a direct teaching away from the present invention. In re Baird, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994); also see the cases cited in MPEP 2141.02 VI and the cases cited therein.

Trogolo teaches microcapsules comprising an antimicrobial agent, typically in the form of a particle or particles encapsulated within a hydrophilic polymer. See Summary of the Invention.

Trogolo teaches a method of preparing an antimicrobial resin by incorporating an antimicrobial microcapsule into a polymer matrix.

Trogolo, however, does not teach latex polymers as either the encapsulating polymers or the matrix polymers. Trogolo actually teaches away from such a process at paragraph [0081], where the advantages of thermal/melt processing are disclosed, which advantages may be considered unique to the process disclosed and essential to the enhanced antimicrobial functioning of the resulting articles. See, e.g., MPEP 2141.02 VI and the cases cited therein. Also see the authorities cited above with respect to Umemura.

The rejection relies on the combination of two references each of which teaches directly away from the present claims. The use of insoluble or encapsulated silver compounds in the process of Umemura would have rendered it essentially inoperable. Similarly, the use of a latex and soluble silver compounds in the process of Trogolo would have rendered that process inoperable.

Thus the combination of teachings is directly contrary to what one of ordinary skill would have done with any expectation of success. See MPEP 2143.02 and the cases cited therein. At the very least, the combination would have been unwarranted by the disclosure of the references. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q 1125 (Fed. Cir. 1984), *Carl Schenk, A.G. v. Norton Corporation*, 713 F.2d 782, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983), *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959), MPEP 2143.01, last paragraph. Consequently, the rejection could only have been based on undue hindsight reconstruction of the references. MPEP 2142, second paragraph, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d

1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985)

McGlothlin has been relied on only as a teaching of equivalence between polymer solutions and latexes for dip molding various medical devices. There is no teaching in McGlothlin pertaining to antimicrobials, either soluble or as microparticles. Thus this reference adds nothing relevant to the combination of references discussed above.

Reconsideration and withdrawal of the rejection of claims 1-23 under 35 U.S.C. 103 is respectfully requested.

CONCLUSION

Applicant submits that all of the claims in this application are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,

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